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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/662,454	09/14/2000	Masayuki Yanagi	2026-4276US1	9114

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EXAMINER

LEFFERS JR, GERALD G

ART UNIT PAPER NUMBER

1636

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/662,454

Applicant(s)

YANAGI, ET AL.

Examiner

Gerald G Leffers Jr., PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 42, 45, 48, 51-53 and 55-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 42 and 45 is/are allowed.
- 6) ☒ Claim(s) 48, 51-53 and 55-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

#### ***Response to Amendment***

Receipt is acknowledged of an amendment, filed 9/23/2004, in which claims were cancelled (claims 46-47 & 49-50) and in which claims were amended (claims 42, 45, 48 & 51-53). Claims 42, 45, 48, 51-53 and 55-57 are pending and under consideration in the instant office action.

Any rejection of record not addressed herein is withdrawn. This action is FINAL.

#### ***Terminal Disclaimer***

The terminal disclaimer filed on 11/1/2004 disclaiming the terminal portion of any patent granted on this application that would extend beyond the expiration date of U.S. Patent No. 6,153,421 has been reviewed and is accepted. The terminal disclaimer has been recorded.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 48, 51-53 & 55-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

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claimed invention. ***This is a new rejection necessitated by applicants' amendment of the claims in the papers filed 9/23/2004.***

Claims 48 and 51 have been amended to recite, "...to produce a chimeric nucleic acid sequence such that infectious nucleic acid sequence of 1b strain having SEQ ID NO: 3 is used to produce a chimera with sequence from the genome of another strain of HCV from a different genotype or subtype." Claim 53 has been amended to recite, "...to produce a deletion of the infectious nucleic acid sequence such that infectious nucleic acid sequence of 1b strain having SEQ ID NO: 3 is used to produce a deletion." There is no literal or inherent support in the originally filed specification and claims for either of the cited limitations. Further, as currently written, there does not appear to be any limitation that the chimeric nucleic acid encode an HCV polypeptide that comprises any part of SEQ ID NO: 3. Thus, the amended claims appear to be drawn to encompass a genus of chimeric nucleic acid molecules that are not supported by the originally filed specification and claims. Therefore, the newly added limitations cited above are impermissible NEW MATTER.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 48, 51-53 & 55-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. ***This is a new rejection necessitated by applicants' amendment of the claims in the papers filed 9/23/2004.***

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Claims 48 and 51 have been amended to recite, "...to produce a chimeric nucleic acid sequence such that infectious nucleic acid sequence of 1b strain having SEQ ID NO: 3 is used to produce a chimera with sequence from the genome of another strain of HCV from a different genotype or subtype." Claim 53 has been amended to recite, "...to produce a deletion of the infectious nucleic acid sequence such that infectious nucleic acid sequence of 1b strain having SEQ ID NO: 3 is used to produce a deletion." In each case it is unclear as to what structural/functional characteristics are conveyed by the cited term. It appears, based upon prosecution history of the instant specification, that applicants are attempting to claim chimeric nucleic acid molecules that encode chimeric proviral polypeptides that comprise portions of SEQ ID NO: 3. As written however, there is no apparent requirement that the chimeric nucleic acids encode any part of SEQ ID NO: 3 at all, much less which portion. Further, it appears the limitation is intended to be a "product by process" type limitation, but it appears to imply an active methods step (i.e. "is used to") in the middle of a composition claim, which is improper. It would be remedial to amend the claim language of the rejected claims to clearly indicate what type of chimeric polypeptide is encoded by the chimeric nucleic acid of the invention, including clear delineation of that which is obtained from a nucleic acid encoding SEQ ID NO: 3.

### ***Conclusion***

Claims 42 and 45 are allowed. Claims 48, 51-53 and 55-57 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gerald G Leffers Jr., PhD  
Primary Examiner  
Art Unit 1636

ggl

  
GERRY LEFFERS  
PRIMARY EXAMINER